

VPA10996/241/001

**NUFLOR Swine 300 mg/ml Solution for injection**

Variation	Summary	Date
Vet - F.I.f.1	VRA-S - Vet - F.I.f.1 - 1. Substantial changes in the updated version of the ASMF or the active substance part of the dossier - F.I.f.1 Quality Changes - Active Substance - Other changes to the active substance - Substantial changes in the updated version of the ASMF or the active substance part of the dossier	03/03/25
Vet - G.I.18	VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	05/12/24
Vet - F.I.b.1 z)	VRA-R - Vet - F.I.b.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.b.1 z) Quality Changes - Active Substance - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	12/01/24
Vet - C2	VNRA - Vet - C2 - Change(s) in the Summary of Product Characteristics (SPC), labelling or package leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6 - C2 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the Summary of Product Characteristics (SPC), labelling or package leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6	30/11/23
Vet - B11 b)	VNRA - Vet - B11 b) - b) Tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance - B11 b) Changes to the quality part of the dossier: Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing	14/02/23

	process of the active substance or of the immediate packaging of the active substance — tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance	
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